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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/406,269      | 09/24/1999  | JIN-AN JIAO          | 48551               | 1426             |

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01/30/2003

DIKE, BRONSTEIN, ROBERTS & CUSHMAN  
INTELLECTUAL PROPERTY PRACTICE GROUP  
EDWARDS & ANGELL  
P.O. BOX 9169  
BOSTON, MA 02209

EXAMINER

VOLLANO, JEAN F

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 01/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/406,269

Applicant(s)

JIAO ET AL.

Examiner

Jean F. Vollano

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 64-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 64-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

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### DETAILED ACTION

1. The amendment filed 1/14/2003 has been entered. Claims 64-77 and newly added claims 78-79 are pending.

2. The 35 U.S.C. 112, first paragraph rejection over claims 64-77 is withdrawn due to the amendment.

3. The 35 U.S.C. 112, 2nd paragraph rejection concerning post operative complications and preferably is moot since that terms have been canceled in the claims.

The 35 U.S.C. 112, paragraph 2 rejection concerning Claims 73-77 and 67-71 and the recitation of "the compound comprises" is maintained .

The 35 U.S.C. 112, paragraph 2 rejection concerning the formula which has  $(\text{PO}_3)_{3-p}$ . The examiner notes that the  $\text{PO}_3$  is not a structural moiety without a charge on the  $\text{PO}_3$  of -2 or without two hydrogens. However reviewing the rejection and specification and looking at the formulas on page 21 wherein the  $\text{PO}_3$  groups are structurally drawn one would understand that the acid or the salt of the acid were the only options for the  $\text{PO}_3$  group and therefore the rejection is withdrawn.

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4. The claims have been limited to “a blood coagulation disorder” and therefore the rejections of the claims 64,-67, 69, 71-73, 75 and 77 under 35 U.S.C. 102(a) as being anticipated by Chem abs653 ( CA:123:33653); claims 64,-67, 69, 71-73, 75 and 77 under 35 U.S.C. 102(a) as being anticipated by Chem abs 868 ( CA:121:179868); claims 64-67, and 70 under 35 U.S.C. 102(b) as being anticipated by Schwab et al (US 5,006,515); claims 64-66, 68-72, and 74-77 under 35 U.S.C. 102(a) as being anticipated by Chem abs 705 ( CA:99:212705); claims 64-66, 68-69, 71-72, 74-75 and 77 under 35 U.S.C. 102(a) as being anticipated by Chem abs 121 ( CA:107:59121); Claims 64-67, and 70 under 35 U.S.C. 102(b) as being anticipated by Chem abs 633 ( CA:126:324966); Claims 64-66, 68, 70 under 35 U.S.C. 102(e) as being anticipated by Hartmann et al (US5854227); claims 64-66, 68-71, 72, and 75-77 under 35 U.S.C. 102(a) as being anticipated by Chem abs820 ( CA:130:209820). and Claims 64-66, 68, 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehtinen et al (US5403829) are moot since they do not concern blood coagulation disorder.

5. The rejection of claims 64,-67, 69, 71-73, 75 and 77 under 35 U.S.C. 102(a) as being anticipated by Chem abs653 ( CA:123:33653) is maintained for reasons of record .

***Claim Rejections - 35 U.S.C. § 112***

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6. Claims 78 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 78 and 79 recite the limitation of “susceptible to undesired thrombosis”.

The claim is confusing as to what is “desired” thrombosis versus “undesired” thrombosis? Is there a thrombosis that is desired? The claim in terms of undesired is confusing as to the metes and bounds of what is being claimed. This part of the rejection can be overcome by deleting the word “undesired”.

The claim is also unclear as to what is meant by “susceptible to”. Does this mean that there are only certain people that may develop thrombosis? Or does this mean that the population being claimed is those who have had previous thrombotic episodes which have been treated and are dormant? The claim is confusing as to the metes and bounds of what is being claimed as the instant invention.

Claims 78 and 79 are also objected to as not being further limiting. Claims 64 and 72 recite ” A method for treating a mammal suffering from a blood disorder”. There is no mention of a population which is “susceptible to”. The claim is not further limiting but broadening.

7. Claims 68, 70, 74, 76 and 78-79 are free of prior art.

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The prior art does not anticipate or suggest the method of use of the compounds with structures found in claims 68, 70, 74 and 76. Nor does the prior art teach the method of use of the compounds in claims 64 and 72 for treating thrombosis as claimed in claims 78-79.

### *Response to Arguments*

8. Applicant's arguments filed 1/14/2003 have been fully considered but they are not persuasive.

In reference to the 35 U.S.C. 112, 2nd paragraph rejection over the terminology of "the compound comprises, Applicant argues that such language is recited in numerous issued U.S. patents, indicating that the language is acceptable under Section 112, second paragraph."

The examiner will not comment on any other US application that is not before the examiner. However using the analogy of applicant- the examiner has given this rejection numerous times before and by applicant's analogy then the language would not be acceptable under Section 112, second paragraph. This Boolean logic can be deceptive in its conclusions.

The fact is that the argument above did not address the examiner's reasons for the rejection or the suggestions given for changing the confusing language. The examiner essentially stated that a compound is a discrete functional unit in which all the atoms are known. A compound doesn't comprise. A composition comprises. Therefore the term is confusing as to whether the phosphate etc are on another compound which is mixed in with the compound of

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formula I or if the phosphate etc are part of the compound. If they are in the compound more descriptive way to write the claim is " the compound contains one phosphate" , "the compound where subscript p is 2".

The reasons for the rejection have been stated and applicant has given no substantial rebuttal to the reasons given. The rejection is maintained.

In reference to the 35 U.S.C. 102(b) rejection of claims 64,-67, 69, 71-73, 75 and 77 as being anticipated by Chem abs653 ( CA:123:33653), Applicant argues that "the cited documents do not describe the diseases or disorders recited in independent claims 64 and 72".

Chem 653 teaches that the compounds of formula I are used to inhibit the endothelin converting enzyme in blood coagulation disorders. The examiner does not know why applicant stated the generic statement above this rejection since it does describe the disease or disorders recited in independent claims 64 and 72. However it does cite blood coagulation disorders and the rejection is maintained.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

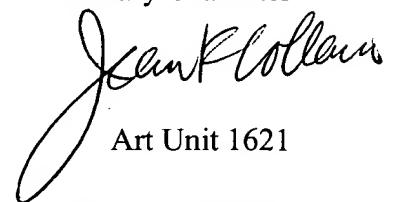
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr J F Vollano whose telephone number is (703) 305-4483. The examiner can normally be reached on Monday to Thursday from 6:30 to 5:00 .

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter , can be reached on (703)308-4532 . The official fax phone number for the organization where this application or proceeding is assigned is (703)308-4556. It should be noted that the examiner cannot immediately work on a fax sent to this number.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

Jean F. Vollano

Primary Examiner

A handwritten signature in black ink, appearing to read "Jean F. Vollano", is written over the printed name and title.

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January 28, 2003